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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,210	12/16/2003	Peter T. Cheng	LA29a DIV-4	7665
23914	7590	04/04/2005	EXAMINER	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			SACKY, EBENEZER O	
		ART UNIT		PAPER NUMBER
		1626		
DATE MAILED: 04/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/737,210 EBENEZER SACKY	CHENG ET AL. Art Unit 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on I.D.S. filed 12/16/03 and 03/16/05 respe.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,5,10,16,18,20,34,37,39,40,50,55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 37,39,40,50,55 and 56 is/are allowed.
- 6) Claim(s) 2,5,10,16,18,20 and 34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/03, 03/16/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 2, 5, 10, 16, 18, 20, 34, 37, 39, 40, 50, 55 and 56 are pending.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 2, 5, 10, 16, 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for breast, prostate, colon,

ovarian, gastric and lung malignancies, does not reasonably provide enablement for any and all malignancies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 34 recite a method for treating a malignant disease, which comprises administering to a patient in need of treatment a therapeutically effective amount of compound of claim 34. However, malignant disease(s) covers a wide variety of cancers with various pathways, mechanisms and complexities e.g., bladder, cervix, penis, lung, vagina, gastrointestinal, liver kidney etc. There is no absolute predictability in the art to predict that one drug capable of treating one cancer can be used for another form of cancer. Chemotherapeutic agents are generally useful against a specific neoplasm or cancer and especially with the unpredictability in the state of the art, there are currently no drugs broadly effective against all forms of cancer because different types of malignancies or cancer affect different organs and have different mechanisms and pathway of growth. Additionally, there is no clinical data or evidence of record to show that there is a reasonable correlation of success for the variety of cancers urged treatable by compounds of claim 34. As discussed above, examples of various cancers are found on page 16 of the specification without any evidence to correlate a reasonable success of their treatment. Applicant's limited examples do not enable one of ordinary skill in the art to treat the numerous amounts of diseases encompassed by the instant claim. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. Further, their mode of action is often unknown or very unpredictable and administration of the drugs

can be accompanied by undesirable side effects. Thus, in the absence of a showing of a correlation between all malignant diseases claimed as capable of being treated by compounds of the instant claim, one of ordinary skill in the art is unable to fully predict possible results from the administration of the compounds due to the unpredictability and variety of malignant diseases. Note *Genentec Inc. V. Novo Nordisk A/S* (CAFC) 42 USPQ 2D 1001, states that:

"a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Hence, it is not reasonable for any agent to be able to generally treat all malignancies.

This rejection can be overcome by reciting specific closely related diseases.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 2, 5, 10, 16, 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "early malignant" and "malignant disease" is of indeterminate scope. What are the parameters of ascertaining when a disease is of its early infancy? Is there a time limit? And if so what is it? What type of malignant disease is being treated? Is there a dosage regimen?

Claims 37, 39-40, 50, 55 and 56 are allowed over the prior art of record, DE 19943635 which differs from the instant compounds employed for treating various ailments in that it discloses a 4-[[carboxyalkyl] amino] methyl] benzoates compounds. The said compounds do not have an oxazole or thiazole substitution on the methylene chain between the two benzene rings or the pharmaceutical combination claimed with the compound. Thus, the compounds employed are neither taught nor anticipated by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.
EOS
March 26, 2005

Joseph K. McKane
Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1